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SONOTRAX 510K SUBMISSION

MAY 25 2004

**510k Submission , SONOTRAX  
Ultrasonic Fetal Pocket Doppler  
Edan Instruments, Inc.**

## SUMMARY

This summary of 510k safety and effectiveness information is being submitted in Accordance with 21CFD part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

Name: Edan Instruments, Inc  
4/F, New Energy Building  
2009 Nanyou Road  
Nanshan, Shenzhen Guangdong  
518054 China  
Phone: 86 755 26062059  
Fax: 86 755 26062022  
Responsible person: Xie Xicheng

Official Correspondent:

William Stern  
Multigon Industries, Inc.  
1 Odell Plaza  
Yonkers, N.Y. 10701  
Phone: 914 376 5200 x27  
Fax: 914 376 5565

Date of Preparation: 2/19/04

2. Device:

Proprietary Name: Sontotrax Ultrasonic Pocket Doppler  
Common Name: Ultrasonic Fetal Monitor  
Classification Name: Fetal Ultrasonic Monitor and Accessories  
Product Code: KNG  
Manufactured By: Edan Instruments, Inc., China

## 3. Predicate Devices:

K010889, Baby Dopplex 3000MK 2, Huntleigh Healthcare Inc. UK.  
K991441, Cadence Doppler Ultrasound System, Medasonics, Inc.  
K942441, Imexdop CT+, Imex Medical Systems, Inc. Golden, CO.  
K023618, Sonicaid One Fetal Heart Detector, UK

## 4. Classification Names :

Class II as per 21CFR 884-2660, Fetal Ultrasonic Monitor and accessories.

## 5. Description:

The Sonotrax fetal Doppler uses the tried and true principle of Doppler shift Of an ultrasound signal to detect the blood flow within the fetal heart and arteries.

The Sonotrax Fetal Doppler uses a split D piezoelectric transducer. A high frequency oscillator supplies a continuous high frequency voltage to one half of the split D transmitter transducer. The high frequency voltage is converted to an ultrasound acoustic wave by the transducer and is transmitted to biophysical objects thru an applied coupling water based medium and moves thru biophysical objects. The acoustic ultrasound is reflected by blood, and moving objects such as the fetal heart. The reflected ultrasound is received by the second split D receiver transducer and is converted via the piezoelectric effect into a high frequency electronic signal. The received electronic signal is amplified and detected. The result is a base band audio Doppler shifted signal which is filtered, and converted to audio via a loud speaker. At the same time the fetal heart rate is applied to and displayed on a liquid crystal counter display.

## 6. Indications for use:

Detection of fetal life from early gestation thru delivery and as a general indication of fetal well being. It can also be used to verify fetal heart viability following patient trauma.

## 7. Contra-indications:

None known at this time.

## 8. Comparison to Predicate Devices:

The Sonotrax Basic fetal Doppler has the same device characteristics as all the predicate approved devices in item 3 above.

9. Test Data:

The Sonotrax Basic Fetal Doppler device has been subjected to extensive safety, performance testing and validations before release. Final testing of the Sonotrax basic fetal Doppler includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

The Sonotrax Basic Fetal Doppler device labeling includes instructions for safe and effective use, warnings cautions and guidance for use.

10. Literature Review:

A review of the literature pertaining to the safety of Doppler Blood flowmeter Has been conducted and appropriate safeguards have been incorporated in the design of the Sonotrax Basic fetal Doppler.

10. Conclusions:

The conclusion drawn from these tests is that the Sonotrax Basic fetal Doppler device is equivalent in safety and efficacy to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 25 2004

Edan Instruments, Inc.  
% Mr. William Stern  
Official Correspondent  
Multigon Industries, Inc.  
1 Odell Plaza  
YONKERS NY 10701

Re: K040480  
Trade/Device Name: Sonotrax Ultrasonic  
Pocket Doppler  
Regulation Number: 21 CFR 884.2660  
Regulation Name: Fetal ultrasonic monitor  
and accessories  
Regulatory Class: II  
Product Code: 85 KNG  
Dated: February 23, 2004  
Received: February 25, 2004

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to, registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

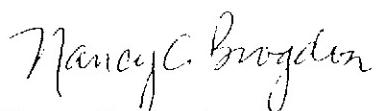
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k040480

Device Name: SONOTRAX Ultrasonic Pocket Doppler

Indications For Use:

Detection of fetal heartbeat from early gestation thru delivery. Verify fetal heart viability after patient trauma. Display of fetal heart rate.

Prescription Device:

Federal Law (US) restricts this device to sale by or on order of a physician.  
Under the direction of a physician it may be used by other health care professionals  
including Registered Nurses, Practical Nurses , Midwives, and Ultrasound Technicians

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K040480

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